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IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

BOLAR PHARMACEUTICAL CO.,

Petitioner,

v.

CIBA-GEIGY CORPORATION,

Respondent.

On a Petition For A Writ of Certiorari To The United States Court Of Appeals For The Third Circuit

BRIEF OF *AMICUS CURIAE* THE NATIONAL COUNCIL OF SENIOR CITIZENS IN SUPPORT OF REVERSAL

JAMES F. FLUG
DIANE BARZMAN
LOBEL, NOVINS & LAMONT
1275 K Street, N.W.
Suite 770
Washington, D.C. 20005
(202) 371-6626

Attorneys for Amicus Curiae

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BRIEF OF *AMICUS CURIAE* THE NATIONAL COUNCIL OF SENIOR CITIZENS

INTEREST OF THE NATIONAL COUNCIL OF SENIOR CITIZENS

The National Council of Senior Citizens (NCSC) of 925 15th Street, N.W., Washington, D.C. 20002, pursuant to Rule 36.1 of the Rules of the United States Supreme Court, files the attached brief Amicus Curiae on a Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit.

The National Council of Senior Citizens ("NCSC") is a not-for-profit membership organization of over four thousand affiliated local associations having a membership of over four million senior citizens.

The National Council of Senior Citizens advocates the interests of senior citizens concerning governmental regulations, legislation and judicial decisions in areas of health care that affect the elderly, particularly including decisions which will adversely affect the health care interests of senior citizens.

The National Council of Senior Citizens was initially formed as an advocate for proper health care for the elderly; it fought for enactment of the legislation establishing the Medicare program, and has vigorously opposed efforts to dilute that program. Recognizing that retired persons and other senior citizens cannot expect medical care superior to or more cost-effective than that which is available to all of the population, the four million plus senior citizens it represents are vitally interested in the quality and the cost of health care programs for all Americans.

One aspect of medical care that places a particularly heavy burden upon the elderly is the cost of medication. This cost is not adequately covered by Medicare or by the most widely used Medicare supplemental health insurance policies. Moreover, the cost of medication has been increasing more rapidly than cost of living increases in Social Security, upon which many elderly persons rely as a principal source of income.

It has been estimated that the elderly spend nearly 20 times more on pharmaceutical expenses, as a percentage of income, than the rest of the population. The National Council of Senior Citizens has both anecdotal and statistical evidence that the high cost of drugs is a burden upon the

elderly, which may in some cases even prevent senior citizens from following drug regimens prescribed for them. Often such drug regimens control symptoms or manage diseases so as to prevent more costly medical treatment.

The decisions of the lower courts in this case adversely affect the rights of senior citizens to purchase medication from competitive sources in the accustomed appearance which they use to recognize and identify their drugs. The elderly do not want to be forced to pay for exorbitant and unnecessary "detailing" and advertising costs and profits to a former patent monopolist, long after a patent has expired on a drug they need and want in recognizable form to maintain their health. The lower courts' decisions artificially establish one monopoly source for formerly patented drugs in their accustomed form.

NCSC has considerable anecdotal evidence from its members of the hardships which artificially inflated drug prices can impose upon them. NCSC, and the other major membership organizations of the elderly, provide pharmacy services at discount prices for their members and rely on the competition provided by generic drug manufacturers to reduce drug costs.

Appearance is important to medicine users. Many of the elderly follow their regimen by color codes—the "blue pill" and the "green pill" in the morning, and the "orange pill" at bedtime, etc. This habit is strong among many users, but is particularly strong among the elderly. The lower courts' decisions will interfere with the availability and utility of reasonably priced generic drugs to NCSC members, to others of the elderly population, and to all citizens.

Not only do the lower courts' decisions grant a monopoly on the very appearance which senior citizens use to recognize, identify, and distinguish among their medications, but

they also grant a monopoly on the *only useful* name provided by the former patent monopolist for the drug.

For these reasons, the NCSC believes that the intent of Congress and of the generic drug substitution laws of the various States is being circumvented, and the health of its members and other senior citizens is being endangered, by the lower courts' decisions.

ARGUMENT

I. The Lower Courts' Decisions Impede Competition By Granting A Perpetual Monopoly On The Reproduction Of A Feature Which Contributes Directly To The Sale Of The Underlying Product, And Are Contrary To The Public Interest

Consumers, particularly senior citizens, recognize and identify their drugs by the accustomed appearance of the drugs. When drug patents expire, senior citizens should be entitled to have competitors manufacture drugs in the accustomed dosage form of the drug. This right was clearly established by this Court in *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111 (1938) at page 120:

> Where an article may be manufactured by all, a particular manufacturer can no more assert exclusive rights *in a form in which the public has become accustomed to see the article* and which, in the minds of the public, is primarily associated with the article rather than a particular producer, than it can in the case of a name with similar connections in the public mind. [emphasis supplied]

In its recent decision in *Inwood Laboratories, Inc. et al.*, v. *Ives Laboratories, Inc.*, 456 U.S. 844 (1982), this Court properly recognized the utility of drug appearance for drug identification, health and safety purposes unrelated to any

trademark purpose, in affirming the District Court decision:

> . . . that the blue and blue-red colors were functional to patients as well as doctors and hospitals: many elderly patients associate color with therapeutic effect; some patients co-mingle medications in a container and rely on color to differentiate one from another; colors are of some, if limited, help in identifying drugs in emergency situations; and use of the same color for brand name drugs and their generic equivalents helps avoid confusion on the part of those responsible for dispensing drugs. [456 U.S. at 853.]

The NCSC fully supports these factors of drug appearance utility approved by this Court in the *Inwood* case. These factors have been improperly disregarded by the lower courts in the Petitioner's case.

Moreover, the lower courts inaccurately characterized the public's interest in having generic drugs in the same color as the brand name, when they asserted that:

> Even in the case of legal substitution, Bolar's conduct endangers the public interest . . . . [S]uch similarity may cause the patient to make the unwarranted assumption that the medication is identical and from the same manufacturer as the prior medication.

Ciba-Geigy Corp. v. Bolar Pharmaceutical Co., Inc., 747 F.2d 844, 853 (3rd Cir. 1984), quoting *Ciba-Geigy Corp. v. Bolar Pharmaceutical Co., Inc.*, 547 F. Supp. 1095, 1109 (D.N.J. 1982). Generic drugs can be easily distinguished by their distinctively low prices. For example, generic Apresoline (an active ingredient in Apresazide used separately by some seniors), sells for only $2.61 for 100 25mg capsules, while its brand counterpart costs $13.61 for the same quan-

tity. Giant Drug Store Advertisement, *The Washington Post*, p. A-13, April 17, 1985.[1] The senior citizen who has been paying $13.61, and now is offered the same medication for $2.61, knows that he or she is getting the generic *without* even looking in the container. But when night comes and that senior citizen, alone at home, opens the container to take the usual "one little blue, two red and white, and one big orange", he or she shouldn't have to deal with a whole new color scheme to enjoy that cost saving.

The cost savings offered by generic drugs are desperately needed by senior citizens, many of whom live on fixed incomes. Bolar's efforts to sell a generic version of Apresazide at a lower price in a recognizable color is of great benefit to senior citizens and clearly is *beneficial* to the public interest. This concrete and important benefit overwhelmingly outweighs the mere speculative possibility that some pharmacist might somewhere risk criminal liability and loss of license by trying to cheat "patients . . . over the age of 60 years . . . [who don't have] sufficiently acute eyesight to detect the difference" between the clear imprint on the tablet, showing the source, and a mislabelled prescription. 747 F.2d at 851, quoting 547 F. Supp. at 1103. The pharmacists most seniors deal with pride themselves on helping seniors, on offering them the best service at the lowest cost, and, particularly, on offering them the lower cost generic alternative where it is available.

The outcome of these cases should not depend on which side of the Hudson River a "brand name" drug company decides to sue a generic drug manufacturer. The NCSC respectfully urges the Court to establish, throughout the

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[1]Current D.C. area ads do not list Apresazide prices, but an inquiry to the same chain indicates that the brand name currently sells for over 50% more than the generic.

United States, that the appearance of a drug product, which is the means consumers have had to recognize and identify the drug during the term of a patent monopoly, cannot continue to be monopolized under an unwarranted and improper extension of the trademark laws after expiration of a patent.

II. The Lower Courts' Decisions Grant A Monopoly On The Only Useful Name For A Prescription Drug

The District Court, affirmed by the Third Circuit Court of Appeals, in order to support its injunction, held that "Hydralazine Hydrochloride and Hydrochlorothiazide" is the generic name for the drug in suit. However, the only useful name known by consumers is "Apresazide", the claimed brand name.

None of the Ciba-Geigy's advertisements promoting "Apresazide" shows a useful generic name. Contrary to the court decision, a complicated list of ingredients—"Hydralazine Hydrochloride and Hydrochlorothiazide"—is not a useful generic name for senior citizens, or other persons, to remember and use as the name for their drug.

This decision conflicts with the policies of the Trademark laws and Food, Drug and Cosmetic laws by granting respondent a monopoly on the only useful name for a prescription drug. When enacting the trademark laws, Congress required that a name which is or becomes the "common descriptive name" of a drug not be monopolized as a trademark. 15 U.S.C. §§ 1064(c), 1065(4). Later, in 1962, because of drug companies' failures to list the generic name, or because of listing it in type too small a size, and because of abuses such as the spectacle of a large manufacturer of drugs failing to designate any generic name at all, Congress enacted 21 U.S.C. § 352(n) to require all prescription drug

promotions to have a generic name printed in type at least half as large as that used for the claimed tradename.[2]

Accordingly, it is the policy of the Trademark laws and the 1962 Amendments to the Food, Drug and Cosmetic laws to require "brand name" drug companies to provide and promote a generic drug name which can be remembered and used easily by persons who do not have a degree in pharmaceutical chemistry. The only useful name provided by Ciba-Geigy for senior citizens and other consumers is "Apresazide," which must necessarily be used as "the name for a drug in whose curative properties they had got confidence". *Bayer Co., Inc. v. United Drug Co.*, 272 F. 505, 510 (S.D.N.Y. 1921) (L.Hand). The decisions of the lower courts frustrate the policy of these laws.

III. The Lower Courts' Decisions Interfere With State And Federal Law And Policy Promoting Use Of Generic Drugs

The lower courts' decisions also interfere with the policy of state generic drug substitution laws enacted by all 50 states. Although the lower courts acknowledge that the known appearance of a drug facilitates patient acceptance and generic substitution by doctors and pharmacists, which is the purpose of the state generic substitution laws, the decisions nevertheless prohibit the manufacture and sale of such drugs.

That the judicial grant of a drug appearance monopoly interferes with the state substitution laws was argued by the New York Attorney General in his Amicus Brief in the

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[2]Respondent's advertising of its Singoserp, Nupercaine and Privine products was cited in Congress as an example of the practices which were to be prevented by the 1962 Amendments. Hearings before the Subcommittee on Antitrust and Monopoly of the Senate Committee on Judiciary, 87th Cong., 2nd Sess. (3374-3403) (1962) Trial R. at 982, 987-990.

Inwood case, and was acknowledged by Justice White in his concurring opinion in *Inwood Laboratories, Inc. et al. v. Ives Laboratories, Inc.*, 456 U.S. 844, 861 (1982):

> Preventing the use of generic drugs of the same color to which customers had become accustomed in their prior use of the brand name product interferes with the important state policy, expressed in New York and 47 other states, of promoting the substitution of generic formulations.

The lower courts' decisions also impede the policy of recent federal law to remove anti-competitive barriers to the marketing of generic drugs. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 ("the Act") to erase the "serious anti-competitive effects" of FDA's previous "cumbersome approval process" for generic drugs. H.R. Rep. 857, Part 2, 98th Cong., 2d Sess. at 4-5 (1984).

The Act was a response to widespread consensus that existing FDA procedures were obstructing rather than facilitating competition in prescription pharmaceuticals:

> Currently, there are approximately 150 drugs approved after 1962 that are off patent and for which there is no generic equivalent. All of these drugs could be approved in generic form if there was a procedure. Each year, more pioneer drugs go off patent and become available as generics . . . . Moreover, the lack of generics for post-1962 pioneer drugs will cost Federal and State governments millions of dollars.

H.R. Rep. 857, Part 1, 98th Cong., 2d Sess. at 17 (1984).

The Act expressed a national policy aimed at getting more generic drugs out on the market sooner:

- The availability of generic versions of pioneer drugs approved after 1962 would save American consumers $920 million over the next 12 years. Older Americans, in particular, would benefit because they use almost 25 percent of all prescription drugs.

Id.

If brand name companies are permitted to monopolize the functional colors of their drug products, generic drug companies will be frustrated in their efforts to compete by selling for less money drugs with publicly familiar appearances, and Congress' efforts to support generic drug competition will be thwarted.

CONCLUSION

Amicus has a strong interest in encouraging competition within the pharmaceutical industry. Granting a perpetual monopoly on product appearance despite its functional character would seriously erode such competitive forces.

WHEREFORE, the National Council of Senior Citizens respectfully requests that this Court grant the Petitioner's request for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit.

Respectfully submitted,

JAMES F. FLUG
DIANE BARZMAN

LOBEL, NOVINS & LAMONT
1275 K Street, N.W.
Suite 770
Washington, D.C. 20005
(202) 371-6626

Attorneys for Amicus Curiae

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